K00 2381

JAN 1 1 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

PENTAFERTE S.L.R , Italy

SUBMITTER INFORMATION

A.	Company Name:	Pentaferte S.R.L.
B.	Company Address:	Zona Industriale 64012
		Campli (Teramo) Italy
B.	Telephone:	+39 861 560201
C.	Fax Number;	+39 861 560200
D.	Contact Person:	Vittorio Servidori, Gen. Dir.
E.	Date Prepared:	July 10, 2000

DEVICE IDENTIFICATION

A.	Generic Device Name:	Hypodermic Syringes with Needle
B.	Trade/Proprietary Name:	Pentaferte® Syringes with Needle
C.	Classification Name:	Piston Syringe (880.5860)
D.	Device Class & Panel:	Class II, Panel 80
E.	Product Code:	FMF (FMI for ~~Insulin syringes~~ needles)

DEVICE DESCRIPTION

The Pentaferte® Syringes are sterile, single-use hypodermic piston syringes intended to inject or withdraw fluids in the body.

The Pentaferte Syringes with Needles are available in assorted sizes: 1cc, 2cc, 2.5cc, 3cc, 5cc, 10cc, 20cc, 30cc, 40cc, 50cc.,and 60cc. With Needle sizes 29G x ½", 28g x1/2", 26G x ½", 25G x 5/8"/ 23G x 1", 23G x 1 ¼", 22G x 1/1/2", 21G x 1 ½", 20G x 1 ½", 19G x 1 ½", and 18G x 1 ½". Hubs are colored coded per international standards for needle gauge. **For Insulin syringes the Needle Cover is Orange.**

Pentaferte offers separate sterile needles, which easily screw onto the Pentaferte Syringes in gauges ranging from 18ga. to 25ga. with lengths ranging from 5/8 to 1 ½ inches. These Needles are Hub colored code according to universal standards for Needle size.

Pentaferte® Syringes with Needles are manufactured at Pentaferte S.L.R., in Italy in a state of the art syringe manufacturing facility which is ISO Certified. The Pentaferte® Syringes with Needles are **CE** marked and distributed all over the world.

INTENDED USE

The Pentaferte® Syringes with Needles are indicated to inject or withdraw fluid in the body. The Insulin Piston syringes are used to administer Insulin.

SUBSTANTIAL EQUIVALENCE

The Pentaferte syringes with Needles are substantially equivalent to the Becton Dickinson Syringes with Needles which was cleared for commercial distribution under 510(k) K94064.

Pentaferte® Syringes with Needles have the same technological characteristics as the Becton dickinson syringes with Needles. Both devices are used to inject or withdraw fluids in the body. Both syringes use the same biocompatible materials in their construction. No significant differences in materials, form, construction, packaging and sterilization exist between these two brands of syringes with needles. **If one or more materials are different, they are still equivalent in their use to manufacture piston syringes and posses equivalent biobompatibility and performance characteristics.**

PERFORMANCE DATA

Performance data provided by Pentaferte S.L.R. indicate that the Pentaferte® Syringes with Needles meet the ISO requirements for Hypodermic syringes with needles and are o substantially equivalent to the Becton Dickinson Syringes with Needles. There are no performance standards established for hypodermic piston syringes. Performance testing was performed per ISO 7886-1 standard and applicable FDA guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Mr. Vittorio Servidori
General Manager
Pentaferte S.R.L
Zona Industriale
Campli Teramo
ITALY

Re: K002381
Trade Name: Pentaferte® Single Use Syringes and Needles
Regulatory Class: II
Product Code: FMF
Dated: October 16, 2000
Received: October 18, 2000

Dear Mr. Servidori:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K002381**

Device Name: Pentaferte® Single Use Syringes and Needles

Indications For Use: The Pentaferte® Single Use Syringes are indicated to inject or withdraw fluids from the body.

Pentaferte Insulin Syringes

The Pentaferte Insulin Syringes are indicated for administration of Insulin for diabetic patients.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDLED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Standard Piston Syringes + Needles OR Over – The - Counter Use ✓ Insulin Syringes with attached Needles U100 only
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, CONFIDENTIAL
and General Hospital Devices
510(k) Number K002381